Debate on the use of arthroscopic surgery for osteoarthritis of the knee

recent article published in the New England Journal of Medicine by J. B. Moseley, an orthopaedic surgeon, and others, was entitled "A controlled trial of arthroscopic surgery for osteoarthritis of the knee" (1). The patients that they studied were all from the Veterans Affairs Medical Center in Houston. They recruited some 180 patients with osteoarthritis of the knee who agreed to be randomized into 1 of 3 groups: a) normal treatment, consisting of lavage and debridement, b) lavage (or saline irrigation) only, and c) a sham operation only, i.e., a nick in the skin but no arthroscopic procedure. Their results suggested that all 3 groups were improved slightly. However, as the placebo group also improved, their conclusion was somewhat damning and extremely far-reaching. They concluded that arthroscopic surgery was obviously of no value in the treatment of arthritis of the knee.

The impact of this article on the public, the insurance industry, and the government has been significant and has raised a great deal of controversy. The conclusions reached by its authors are a good example of why research, particularly clinical research, should be subjected to peer review by experts in that specific field, and results validated, before such information is released to the public.

Our own studies have also shown that arthroscopic surgery is of little value in the more advanced stages of arthritis but can be of significant value in relieving pain and swelling and improving function in the earlier stages of arthritis. A recent study that has been accepted for publication in the *Journal of Arthroscopy* has shown that such benefit can be obtained for at least 4 to 6 years in patients with early stages of arthritis.

Dr. Nelda Wray, one of the authors of the Moseley study, was quoted as saying that "the fact that the effectiveness of arthroscopic lavage and debridement in patients with osteoarthritis of the knee is no greater than that of placebo surgery makes us question whether the \$1 billion spent on these procedures might be put to better use." Dr. Wray is also quoted as saying, "I believe the coffin lid is nailed shut on this procedure." It is noted that Dr. Wray is an internist with a degree in public health and not an orthopaedic surgeon nor an expert in musculoskeletal disease.

The fallout from these statements and others has been significant over the past few months. Patients are questioning their doctors' advice. The Department of Veterans Affairs (VA) in Washington issued a directive on August 23, 2002, recommending that without a review by a panel of experts, arthroscopic procedures for osteoarthritis should not be done in the VA system. If the VA as a government agency is telling surgeons what they

can do and on whom they can operate, how soon will Medicare follow? United Healthcare, a private insurance company, has also written to surgeons that have conducted arthroscopic surgery on arthritic patients and suggested that they critically review the appropriateness of this procedure in this patient population. It is probable that insurers will soon stop paying for the procedure.

The success for patients in this procedure is strongly dependent on selectivity, a factor that is missing from placebo surgery. Experienced surgeons are extremely thorough in selecting their patients with osteoarthritis for arthroscopic surgery and choose those that will benefit most. The implication of this article has been that patients with osteoarthritis of the knee should wait until their knee gets so bad that it requires a total knee replacement. Looking at the economic approach for the validity of such a concept, the cost of the total knee replacement is 5 times greater than that of an arthroscopic lavage and debridement. Also, since total knee replacements frequently have to be redone in several years because they tend to wear, one has to question whether the economics suggested in this article really stand up.

This study was seriously flawed, first by the selection of patients with no clear indication as to how severe the arthritic state was in each case. Second, patients in the VA system do not represent the typical population, which consists of younger people and women (97% of study patients were men). Moreover, VA patients have a vested interest in getting continued benefits for a disability. Third, the statistics used in the paper have been strongly criticized by independent statisticians, as the authors changed their direction on 3 occasions, first using an established device to show superiority of one group over another (which it did not), then using another proven device to demonstrate "equivalence" (which it did not), and then finally using an unvalidated measurement device of their own making, which did prove equivalence of the 3 groups.

The best one can say of this article was that it presented preliminary information from a limited study and did not prove or validate the concept of arthroscopic surgery in the treatment of arthritis as a whole.

—ROBERT W. JACKSON, OC, MD, FRCS(C)

Dr. Jackson is chief of the Department of Orthopaedic Surgery at Baylor University Medical Center.

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Moseley JB, O'Malley K, Petersen NJ, Menke TJ, Brody BA, Kuykendall DH, Hollingsworth JC, Ashton CM, Wray NP. A controlled trial of arthroscopic surgery for osteoarthritis of the knee. N Engl J Med 2002;347:81–88.

DR. MOSELEY RESPONDS:

Thank you for the opportunity to respond to Dr. Jackson's letter.

Dr. Jackson, and a vocal number of other arthroscopists, have voiced their disagreement with an article that we published recently in the *New England Journal of Medicine*. Our study found that all of the benefit that patients report after arthroscopy for osteoarthritis of the knee is from a placebo effect. Surgeons like Dr. Jackson who routinely perform arthroscopy for this reason are undoubtedly embarrassed at the prospect that the placebo effect, not surgical skill, is responsible for patient improvement after surgeries they perform. As you might imagine, these surgeons are going to great lengths to try to discredit our study.

Most studies in orthopaedics are retrospective case-control studies in which the surgeons simply report their experience with a procedure and bias is uncontrolled. Dr. Jackson's work on the subject of arthroscopy for osteoarthritis of the knee is typical of this type of study. Retrospective studies have some value, but of all study types they are the most susceptible to misinterpretation. They are the easiest to perform, but they are also the most prone to study error. History has shown that many drugs, treatments, and surgeries initially thought to have benefit on the basis of retrospective studies are later shown to be beneficial mostly or entirely from a placebo effect (1–9).

Our study is unique in orthopaedics. It is a prospective, randomized, controlled clinical trial—the best study design to test a clinical hypothesis. Contrary to what our critics would have you believe, our study was carefully designed, performed, analyzed, and written. It took over 10 years to complete, and it is the output of a clinical research center at the Houston VA Hospital that is recognized for its expertise in clinical research. This study was not the result of one surgeon reporting results that justified his or her preconceived conclusions. This study was the combined effort of many professionals with expertise in surgery, clinical research, ethics, psychology, statistics, sociology, public health, and economics—all committed to rigorous adherence to a study design of the highest quality. The end result of our study was a manuscript that was selected to be the lead article in the July 11, 2002, edition of the New England Journal of Medicine (10)—a rare accomplishment in orthopaedic surgery.

Dr. Jackson and his colleagues would have you believe that critical errors were made in the design, implementation, analysis, and publication of our study. We disagree. The patients in our study were carefully screened and, in our opinion, are representative of the typical American that would seek orthopaedic advice for his or her arthritic knee. An experienced orthopaedic surgeon and arthroscopist recruited all patients and performed all surgeries (JBM). There were roughly equal numbers of mildly, moderately, and severely arthritic knees in our study. We have done subgroup analysis on multiple factors including disability status, and we can find no exceptions to our conclusion that arthroscopy for osteoarthritis of the knee is beneficial only because of a placebo effect (this is the subject of an additional manuscript). Our statistics were not changed because of an inability to prove our hypothesis—it was quite the contrary. We designed our study to prove whether or not one treatment was superior to another. When we found that none of the 3 treatments was statistically superior to the others, we took the extra

step of proving that the 3 treatments were statistically equivalent (a much harder feat).

Dr. Jackson complains that we published our article in a nonorthopaedic journal and it was not subject to orthopaedic peer review. This is not true. The *New England Journal of Medicine* had well-respected orthopaedists review the article, and these reviewers gave it extremely high marks and encouraged the journal to accept it for publication. One of those orthopaedists, Dr. Jody Buckwalter, even wrote a strongly supportive editorial that appeared in the same issue as our article.

Our study is unquestionably controversial. We have shown that a commonly performed surgical procedure is effective only because of a placebo effect, and we have recommended that the procedure not be performed anymore. However, our study has been very well received by a large portion of orthopaedic surgeons, and we have received strong support from the scientists in our profession. It has been the arthroscopists who have gone to great lengths to try to discredit the study. Dr. Jackson and his colleagues have voiced criticisms of practically every aspect of the study, and most have raised reasonable questions that we are happy to answer. However, some of the criticisms, such as the characterization of our statistics, are at best a lack of understanding of our methodology and at worst deliberate misinformation from surgeons trying desperately to protect their practice. There is probably no evidence of any kind that would satisfy this latter group. To this group of disbelievers, we challenge them to provide the scientific data to support their position. We are confident that if every study on this subject undergoes the same scrutiny that ours has, our study will hold up very well, and our conclusions will stand the test of time.

We are indebted to Dr. Robert Jackson and the other pioneers of arthroscopic surgery for leading us to the point where arthroscopy is now the most commonly performed orthopaedic surgery. Without their pioneering leadership, we would not be treating athletes and athletic injuries with minimal disability and a fraction of the recovery time of traditional treatments. However, the time has come for the arthroscopists to provide their peers with evidence of the value of their surgeries in a manner other than "I did a hundred or more of these surgeries and they all did well." Until prospective, randomized, comparative studies become the norm for our profession, we will continue to perform surgeries that may be no more beneficial than nonsurgical treatments or a placebo effect. Our patients and our peers deserve better.

Thank you again for the opportunity to contribute to your journal.

—Bruce Moseley, MD

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- Diamond EG et al. Comparison of internal mammary artery ligation and sham operation for angina pectoris. Am J Cardiol 1959;5:483–486.
- Cobb L et al. An evaluation of internal mammary artery ligation by a double blind technic. N Engl J Med 1959;260:1115–1118.
- de Craen AJ, Moerman DE, Heisterkamp SH, Tytgat GN, Tijssen JG, Kleijnen J. Placebo effect in the treatment of duodenal ulcer. Br J Clin Pharmacol 1999:48:853–860.
- de Craen AJ, Tijssen JG, de Gans J, Kleijnen J. Placebo effect in the acute treatment of migraine: subcutaneous placebos are better than oral placebos. J Neurol 2000;247:183–188.

- Lange RA, Hillis LD. Transmyocardial laser revascularization [editorial]. N Engl J Med 1999;341:1075–1076.
- Hypericum Depression Trial Study Group. Effect of Hypericum perforatum (St John's wort) in major depressive disorder: a randomized controlled trial. JAMA 2002;287:1807–1814.
- Linde C, Gadler F, Kappenberger L, Ryden L. Placebo effect of pacemaker implantation in obstructive hypertrophic cardiomyopathy. PIC Study Group. Pacing In Cardiomyopathy. Am J Cardiol 1999;83:903–907.
- 8. Moerman DE. Cultural variations in the placebo effect: ulcers, anxiety, and blood pressure. *Med Anthropol Q* 2000;14:51–72.
- Amanzio M, Pollo A, Maggi G, Benedetti F. Response variability to analgesics: a role for non-specific activation of endogenous opioids. *Pain* 2001; 90:205–215.
- Moseley JB, O'Malley K, Petersen NJ, Menke TJ, Brody BA, Kuykendall DH, Hollingsworth JC, Ashton CM, Wray NP. A controlled trial of arthroscopic surgery for osteoarthritis of the knee. N Engl J Med 2002;347:81–88.